SoCRATES: Short Course on Clinical Research and Translational Experience in Science

SoCRATES I: 14 October 2014
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Co-Course Directors
Disclosures

I receive partial salary support from the ACTSI.

I have no other financial conflicts of interest related to the content.
Objectives of SoCRATES

At the completion of SoCRATES I & II, the student will be able to:

1. Describe the opportunities for clinical and translational research in the academic setting.
2. Describe the components of a complete “cycle of research” from inception to presentation.
3. Comprehend key biostatistics and epidemiology principles and apply them to their proposed Discovery Phase project.
4. Utilize database management and analytical software.
5. Describe the variety of traditional research and non-traditional research opportunities.
6. Describe the research resources at Emory and be able to incorporate their offerings into their Discovery Phase project.
7. Critically read and assess a published journal article.
SoCRATES is a tool kit for Discovery

SoCRATES I: Oct 14 & 28: 5-7pm
SoCRATES II: May 20-22: 8am-12pm
SoCRATES I Schedule

SoCRATES Part I: October 14 & 28, 2014

Tuesday 14 October 2014
SOM 110

• 17:00 – 18:00 Introduction to SoCRATES (Andi Shane)
• 18:05 – 19:00 ACTSI, Research Resources and Navigating the System (Andi Shane)

Tuesday 28 October 2014
SOM 110

• 17:00 – 17:25 Research study design (Beau Bruce)
• 17:30 – 17:55 Sample size calculations (Beau Bruce)
• 18:00 – 18:15 Writing the statistical section of the Discovery proposal (Beau Bruce)
• 18:15 – 18:55 Introduction to statistical software (Beau Bruce)
SoCRATES II May 20 – 22, 2015
08:00-12:00
If you are scheduled to be in Discovery during May and your project is in the Atlanta metropolitan area, you are required to attend SoCRATES
Assessments

- Knowledge assessment in person (22 May 2015) or online if Discovery project is out of Atlanta
- Attendance is required by the School of Medicine for all hours of SoCRATES when you are scheduled for Discovery weeks and are in metropolitan Atlanta
Discovery: What Do I Need?

- Passion
  - Ideas
  - Mentor
  - Project
  - Proposal
Passion / Ideas

- What fascinates me? What keeps me up at night? What frustrates me?
- What do I like?
- What am I scared to do?
- What makes me happy?
- What might I never have the chance to do again?
## Project Ideas

### List of Research Projects 2016

<table>
<thead>
<tr>
<th>Project ID</th>
<th>Name of Emory Mentor</th>
<th>Department/Division</th>
<th>Email</th>
<th>Project Title</th>
<th>Project Keywords</th>
</tr>
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- Departmental websites
- Former Discovery students
- NIH RePORTER
  - [http://projectreporter.nih.gov/reporter.cfm](http://projectreporter.nih.gov/reporter.cfm)
Mentor 1

• Does this relationship feel right?
• Has this individual mentored Discovery students in the past?
• Does the mentor have time to mentor me?
• How can I be a good mentee?

Project: Traditional Research

Basic Research

Translational Research

“Bench to Bedside”

Clinical Research
Project: “Non-Traditional” Research

• Comparative – effectiveness
  ▪ Quality/ patient-safety
  ▪ Implementation science
Project: Comparative Effectiveness Research

- Compare treatment options for different health conditions

- Improve health care quality by evaluating which medical treatments work best for a given condition

- Compare drugs, medical devices, tests, surgeries, or ways to deliver health care
Project: Quality/ Patient Safety

- Prevent, mitigate, and decrease medical errors, patient safety risks and hazards, and quality gaps associated with health care and their harmful impact on patients.

- Application of clinical science, human and work systems factors, epidemiology, and implementation of safe practices that have successfully improved care.

- Involve health care organizations, providers, policymakers, researchers, patients.

Project: Implementation Science

Creates generalizable knowledge that can be applied across settings

Why do established programs lose effectiveness over days, weeks, or months? Why do tested programs sometimes exhibit unintended effects when transferred to a new setting? How can multiple interventions be effectively packaged to capture cost efficiencies and to reduce the splintering of health systems into disease-specific programs?

Implementation science seeks to understand the behavior in the sustainability, uptake, adoption, and implementation of evidence-based interventions.
Atlanta Clinical & Translational Science Institute

Translating scientific discoveries to impact the Atlanta community, Georgia, & beyond

DISCOVERY TRAINING COMMUNITY
ACTSI Programs

**Biomedical Informatics Program (BIP)**
- Grant writing for informatics
- Programming support
- Data reports from the clinical data warehouse
- Informatics training
- Database design and support
- Data management
- Informatics consultant support
- Study website
- Collaboration workspace
- Laboratory information system support
- Electronic case report form
- Imaging informatics
- Clinical research databases
- High performance and cloud computing design and consulting

**Biostatistics, Epidemiology, & Research Design (BERD)**
program provides prospective design of human studies research, statistical methodologies, elements of data collection and management and analysis of data.
ACTSI Programs (continued)

Clinical Research Network (CRN) - provides support for the conduct of patient-oriented research.

- Research nursing for participant visits, phlebotomy, IV access, medication administration
- Recruitment core support
- Inpatient space for participant visits
- Research pharmacy support
- Bionutrition support
- Clinical Data Extraction Service Center
- Safety oversight
- Atlanta Hospital Hospitality House
- Web-based participant scheduling & protocol tracking
- Lab support for processing, aliquoting, and storage
- Outpatient space for participant visits
- Program director expertise
- Sleep/apnea studies
- Exercise physiology support
- Ancillary lab support
ACTSI Programs (continued)

Community Engagement Research Program (CERP) - creates equitable academic-community partnerships, stimulates community-engaged research, promotes community health and helps train researchers in community engagement.

- Community engagement support
- Assistance with recruitment for patient/clinical trials
- Engage communities
- Disseminate findings to communities
- Assistance in finding a community partner
- Developing community engagement plans
- For communities: assistance in finding a faculty partner
- Assistance in developing academic-community research partnerships
- Delivering health promotion/health education messages
- Consultation in community-based participatory research
- Consultation on designing community intervention trials
**ACTSI Programs (continued)**

**Ethics & Regulatory** - advises and educates researchers on ethical dilemmas.
- Data safety research ethics consultation service
- Data safety monitoring board
- Serious adverse event reporting
- Adverse event reporting
- Research subject advocate's help
- Data safety monitoring plan
- Other Regulatory /IRB / Compliance question
- Good clinical practice in FDA-regulated clinical trials
- Question about conflict of interest
- Consult for consent development

**Pediatrics** - supports the conduct of pediatric clinical and translational research that effectively reaches the entire Atlanta pediatric community.
ACTSI Studio

○ Request a **Studio Appointment** with the Biomedical Informatics Program (BIP), Biostatistics, Epidemiology, & Research Design (BERD) program, and/or the Clinical Research Network (CRN) (Studio)
Questions for SoCRATES 1

1. How important is it to select a Discovery Project with a mentor whose research interest is in my field of interest?
2. What if I don’t know what my field of interest is?
3. What if my field of interest changes?
Questions for SoCRATES 2

1. What do I do if I start a project and I do not like the topic?
2. What do I do if I start a project and the mentor and I have differences?
1. Should I work on more than one Discovery project?
Questions for SoCRATES 4

1. What do I do if I observe an ethical or research breach while working on my Discovery project?
Emory Trustline

- Anonymous reports can be made to the Emory University Trust Line at 1-888-550-8850
- Operated by an independent third party who will maintain the caller’s anonymity, while ensuring that the caller’s report is routed to the proper individuals within the University
- If you make a good faith report of suspected research misconduct, there cannot be any retaliation for making the report.
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